

General

Guideline Title

Guidelines for endoscopy in pregnant and lactating women.

Bibliographic Source(s)

ASGE Standard of Practice Committee, Shergill AK, Ben-Menachem T, Chandrasekhara V, Chathadi K, Decker GA, Evans JA, Early DS, Fanelli RD, Fisher DA, Foley KQ, Fukami N, Hwang JH, Jain R, Jue TL, Khan KM, Lightdale J, Pasha SF, Sharaf RN, Dominitz JA, Cash BD. Guidelines for endoscopy in pregnant and lactating women. Gastrointest Endosc. 2012 Jul;76(1):18-24. [61 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Qureshi WA, Rajan E, Adler DG, Davila RE, Hirota WK, Jacobson BC, Leighton JA, Zuckerman MJ, Hambrick RD, Fanelli RD, Baron T, Faigel DO. ASGE guideline: guidelines for endoscopy in pregnant and lactating women. Gastrointest Endosc 2005 Mar;61(3):357-62. [36 references]

Regulatory Alert

FDA Warning/Regulatory Alert

drugs to warn about these risks.

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

•	December 14, 2016 – General anesthetic and sedation drugs : The U.S. Food and Drug Administration (FDA) is
	warning that repeated or lengthy use of general anesthetic and sedation drugs during surgeries or procedures in children younger than 3
	years or in pregnant women during their third trimester may affect the development of children's brains. Consistent with animal studies,
	recent human studies suggest that a single, relatively short exposure to general anesthetic and sedation drugs in infants or toddlers is unlikely
	to have negative effects on behavior or learning. However, further research is needed to fully characterize how early life anesthetic exposure
	affects children's brain development.
•	August 31, 2016 – Opioid pain and cough medicines combined with benzodiazepines : A U.S. Food and Drug
	Administration (FDA) review has found that the growing combined used of opioid medicines with benzodiazepines or other drugs that
	depress the central nervous system (CNS) has resulted in serious side effects, including slowed or difficult breathing and deaths. FDA is
	adding Boxed Warnings to the drug labeling of prescription opioid pain and prescription opioid cough medicines and benzodiazepines.
•	March 22, 2016 – Opioid pain medicines : The U.S. Food and Drug Administration (FDA) is warning about
	several safety issues with the entire class of opioid pain medicines. These safety risks are potentially harmful interactions with numerous other
	medications, problems with the adrenal glands, and decreased sex hormone levels. They are requiring changes to the labels of all opioid

Recommendations

Major Recommendations

Definitions for the quality of the evidence (++++, ++++O, ++OO, and +OOO) and for the strength of the recommendations ("recommends" or "suggests") are provided at the end of the "Major Recommendations" field.

Recommendations

Pregnancy

- The Practice Committee recommends that endoscopy during pregnancy should be done only when there is a strong indication and should be postponed to the second trimester whenever possible (+OOO).
- The Practice Committee recommends the close involvement of obstetrical staff to assist with management, including determination of the degree of maternal and fetal monitoring (+OOO).
- The Practice Committee suggests that for endoscopic procedures involving moderate sedation during pregnancy, meperidine is the preferred agent followed by small doses of midazolam as needed (+OOO).
- The Practice Committee recommends deep sedation, when needed, be administered by an anesthesia provider (+OOO).
- Therapeutic endoscopic retrograde cholangiopancreatography (ERCP) is generally safe in pregnancy. The Practice Committee recommends that care be taken to minimize radiation exposure to the fetus (++OO) and risks to the mother (++OO).
- The Practice Committee recommends that when electrocautery is required, bipolar electrocautery be used. If monopolar electrocautery must be used, the grounding pad should be placed to minimize flow of electrical current through the amniotic fluid (+OOO).
- The Practice Committee recommends that in late pregnancy, women should be in the lateral decubitus position before, during, and after the procedure (+OOO).
- The Practice Committee recommends that antibiotic choice in the context of endoscopic procedures consider patient-specific factors and stage of fetal development. Although many antibiotics can be safely used in pregnancy, some are contraindicated (quinolones, streptomycin, tetracyclines) while others are safe only in certain stages of fetal development (+++OO).

Lactation

- The Practice Committee suggests that breastfeeding may be continued after maternal fentanyl administration (++OO).
- The Practice Committee suggests that infants not be breastfed for at least 4 hours after maternal midazolam administration (+++OO).
- The Practice Committee suggests that breastfeeding may be continued after maternal propofol administration as soon as the mother has recovered sufficiently from general anesthesia to nurse (++OO).
- The Practice Committee recommends that quinolones and sulfonamides be avoided (+OOO).
- Penicillins, cephalosporins, tetracyclines, and erythromycin are compatible with breastfeeding (+++OO).

<u>Definitions</u>:

GRADE (Grading of Recommendations, Assessment, Development and Evaluation) System for Rating the Quality of Evidence for Guidelines

Quality of Evidence	Definition	Symbol
High quality	Further research is very unlikely to change confidence in the estimate of effect.	++++
Moderate quality	Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.	+++O
Low quality	Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate.	++OO
Very low quality	Any estimate of effect is very uncertain.	+OOO

Adapted from Guyatt GH, Oxman AD, Vist GE, et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ 2008;336:924-6.

The strength of individual recommendations is based on both the aggregate evidence quality and an assessment of the anticipated benefits and harms. Weaker recommendations are indicated by phrases such as "the Practice Committee suggests," whereas stronger recommendations are typically stated as "the Practice Committee recommends."

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

- Pregnancy
- Lactation
- Gastrointestinal (GI) disorders during pregnancy including:
 - Significant or continued GI bleeding
 - Severe or refractory nausea and vomiting or abdominal pain
 - Dysphagia or odynophagia
 - Strong suspicion of colon mass
 - Severe diarrhea with negative evaluation
 - Biliary pancreatitis, symptomatic choledocholithiasis, or cholangitis
 - Biliary or pancreatic ductal injury

Guideline Category

Evaluation

Management

Clinical Specialty

Gastroenterology

Obstetrics and Gynecology

Intended Users

Nurses

Physicians

Guideline Objective(s)

- To provide guidelines for the use of gastrointestinal endoscopy in pregnant and lactating women
- To update the 2005 American Society of Gastrointestinal Endoscopy (ASGE) guideline on this topic

Target Population

Pregnant or lactating women who require gastrointestinal endoscopy

Interventions and Practices Considered

- 1. Performing gastrointestinal endoscopy during pregnancy only for a strong indication with a careful assessment of risk versus benefit
- 2. Postponing endoscopy to the second trimester whenever possible
- 3. Close involvement of obstetrical staff to assist with management, including determination of the degree of maternal and fetal monitoring
- 4. Meperidine, followed by small doses of midazolam as needed, for moderate sedation
- 5. Deep sedation, when needed, administered by an anesthesia provider
- 6. Minimizing radiation exposure during endoscopic retrograde cholangiopancreatography (ERCP)
- 7. Use of bipolar electrocautery in preference to monopolar
- 8. Use of the lateral decubitus position before, during, and after the procedure during late pregnancy
- 9. Consideration of patient-specific factors and stage of fetal development when choosing an antibiotic
- 10. Continuation of breastfeeding after maternal fentanyl and propofol administration
- 11. Avoiding breastfeeding for at least 4 hours after maternal midazolam administration
- 12. Avoiding quinolones and sulfonamides during breastfeeding
- 13. Using penicillins, cephalosporins, tetracyclines, and erythromycin during breastfeeding

Major Outcomes Considered

- Procedural risks of gastrointestinal endoscopy to mother and child during pregnancy and lactation
- Teratogenicity of drugs and/or ionizing radiation exposure used during endoscopy
- The levels of drugs commonly used in endoscopy excreted in breast milk

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

In preparing this guideline, a search of the medical literature by using PubMed was performed. Additional references were obtained from the bibliographies of the identified articles and from recommendations of expert consultants. When few or no data exist from well-designed, prospective trials, emphasis was given to results from large series and reports from recognized experts.

The MEDLINE database was searched through October 2011 for English language articles related to endoscopy in pregnant or lactating patients. For this search, the terms endoscopy, colonoscopy, esophagoduodenoscopy (EGD), endoscopic ultrasound (EUS), endoscopic retrograde cholangiopancreatography (ERCP), sedation and analgesia were searched in combination with the terms pregnancy and lactation. All searches were supplemented by reviewing the "related articles" feature of PubMed and any pertinent references cited by the identified studies. Although emphasis is placed on controlled clinical trials, such data are generally lacking in the pregnant patient population. Thus, case series, preliminary clinical studies, case control studies and expert opinions are utilized. In addition, the National Library of Medicine Drugs and Lactation (LactMed) database was searched to review pertinent drugs.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

GRADE (Grading of Recommendations, Assessment, Development and Evaluation) System for Rating the Quality of Evidence for Guidelines

Quality of Evidence	Definition	Symbol
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Moderate quality	Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.	+++O
Low quality	Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate.	++OO
Very low quality	Any estimate of effect is very uncertain.	+OOO

Adapted from Guyatt GH, Oxman AD, Vist GE, et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. BMJ 2008;336:924-6.

Methods Used to Analyze the Evidence

Systematic Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Guidelines for appropriate use of endoscopy are based on a critical review of the available data and expert consensus. The recommendations are based on reviewed studies and are graded on the strength of the supporting evidence.

Rating Scheme for the Strength of the Recommendations

The strength of individual recommendations is based on both the aggregate evidence quality and an assessment of the anticipated benefits and harms. Weaker recommendations are indicated by phrases such as "the Practice Committee suggests," whereas stronger recommendations are typically stated as "the Practice Committee recommends."

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

This document is a product of the American Society for Gastrointestinal Endoscopy (ASGE) Standards of Practice Committee. This document

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Appropriate and effective use of endoscopy in pregnant and lactating women
- In situations where therapeutic intervention is necessary, endoscopy offers a relatively safe alternative to radiologic or surgical interventions.

Potential Harms

- Gastrointestinal (GI) endoscopy in pregnant patients is inherently risky because the fetus is particularly sensitive to maternal hypoxia and
 hypotension, either of which can cause hypoxia that can lead to fetal demise. Maternal oversedation resulting in hypoventilation or
 hypotension or maternal positioning precipitating inferior vena cava compression by the gravid uterus can lead to decreased uterine blood
 flow and fetal hypoxia. Other risks to the fetus include teratogenesis (from medications given to the mother and/or ionizing radiation
 exposure) and premature birth.
- Caution should be used in administering any level of sedation to a pregnant patient because of the increased risk of aspiration and potentially
 difficult airway. Pregnancy-induced physiologic changes involving the cardiopulmonary and GI systems as well as anatomic changes in the
 airway, such as swelling of the oropharyngeal tissues and decreased caliber of the glottic opening, make careful monitoring of the sedated
 pregnant patient mandatory. Refer to the original guideline document for a discussion of safety of various anesthetic agents used in GI
 endoscopy during pregnancy.
- The safety of polyethylene glycol electrolyte isotonic cathartic solutions has not been studied in pregnancy. Polyethylene glycol solutions are classified as pregnancy category C. Sodium phosphate preparations (category C) may cause fluid and electrolyte abnormalities and should be used with caution.
- Caution should be exercised in the use of certain medications because these drugs may be transferred to the infant through breast milk. In
 situations where there is a concern regarding medication or metabolite transfer to the infant, the woman should be advised to pump her
 breast milk and discard it as indicated for the individual medication after the procedure is complete. Refer to the original guideline document
 and to the "Major Recommendations" field above for additional information on safety during lactation of medications commonly used for
 endoscopy.

Contraindications

Contraindications

- Naloxone is contraindicated in mothers dependent on opiates, because it can precipitate opiate withdrawal symptoms.
- Endoscopy is contraindicated in obstetric complications such as placental abruption, imminent delivery, ruptured membranes, or uncontrolled eclampsia.
- Sulfonamides are contraindicated in breastfeeding mothers of infants who are ill, premature, and glucose-6-phosphate dehydrogenase deficient.
- Although many antibiotics can be safely used in pregnancy, some are contraindicated (quinolones, streptomycin, tetracyclines), while others are safe only in certain stages of fetal development. Refer to Tables 5 and 6 in the original guideline document for a list of antibiotics that can safely be used during pregnancy and lactation and for antibiotics that should be avoided.

Qualifying Statements

Qualifying Statements

- Further controlled clinical studies may be needed to clarify aspects of this guideline. This guideline may be revised as necessary to account for changes in technology, new data, or other aspects of clinical practice.
- This guideline is intended to be an educational device to provide information that may assist endoscopists in providing care to patients. This guideline is not a rule and should not be construed as establishing a legal standard of care or as encouraging, advocating, requiring, or discouraging any particular treatment. Clinical decisions in any particular case involve a complex analysis of the patient's condition and available courses of action. Therefore, clinical considerations may lead an endoscopist to take a course of action that varies from these guidelines.
- The safety and efficacy of gastrointestinal (GI) endoscopy in pregnant patients is not well-studied. Invasive procedures during pregnancy are justified when it is clear that failure to perform the procedure could expose the fetus and/or mother to harm. Informed consent should include risks to the fetus as well as to the mother.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Safety

Identifying Information and Availability

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2005 Mar (revised 2012 July)

Guideline Developer(s)

American Society for Gastrointestinal Endoscopy - Medical Specialty Society

Source(s) of Funding

American Society for Gastrointestinal Endoscopy

Guideline Committee

Standards of Practice Committee of the American Society of Gastrointestinal Endoscopy

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Financial Disclosures/Conflicts of Interest

V. Krishnavec is a speaker for Boston Scientific, and D. Fisher is a consultant for Epigenomics. No other financial relationships relevant to this publication were disclosed.

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Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the American Society for Gastrointestinal Endoscopy (ASGE) Web site

Print copies: Available from the American Society for Gastrointestinal Endoscopy, 1520 Kensington Road, Suite 202, Oak Brook, IL 60523

Availability of Companion Documents

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI on April 8, 2005. This summary was updated by ECRI Institute on January 7, 2009 following the U.S. Food and Drug Administration (FDA) advisory on oral sodium phosphate (OSP) products for bowel cleansing. This summary was updated by ECRI Institute on March 10, 2009, following the U.S. Food and Drug Administration advisory on Topical Anesthetics. This summary was updated by ECRI Institute on May 1, 2009 following the U.S. Food and Drug Administration advisory on antiepileptic drugs. This summary was updated by ECRI Institute on August 21, 2012. This summary was updated by ECRI Institute on June 2, 2016 following the U.S. Food and Drug Administration advisory on opioid pain medicines. This summary was updated by ECRI Institute on October 21, 2016 following the U.S. Food and Drug Administration advisory on opioid pain and cough medicines combined with benzodiazepines. This summary was updated by ECRI Institute on February 15, 2017 following the U.S. Food and Drug Administration advisory on general anesthetic and sedation drugs.

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